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Frank C. Eisenschenk

Frank C. Eisenschenk, Ph.D., Patent Attorney

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
Examining Group 1614
Patent Application
Docket No. MET-016XDT
Serial No. 10/780,948

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner	:	Patrick T. Lewis
Art Unit	:	1614
Applicants	:	Mark D. Erion, Paul D. van Poelje
Serial No.	:	10/780,948
Filed	:	February 17, 2004
Conf. No.	:	2285
For	:	Combination of FBPase Inhibitors and Insulin Sensitizers for the Treatment of Diabetes

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Alexandria, VA 22313

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §§1.97 AND 1.98

Sir:

In accordance with 37 CFR §1.56, the references listed on the attached form PTO/SB/08 are being brought to the attention of the Examiner for consideration in connection with the examination of the above-identified patent application. A copy of each cited reference is enclosed. However, Applicants have not submitted copies of the U.S. patents cited on attached Form PTO/SB/08 pursuant to 37 CFR 1.98(a)(2)(ii).

It is respectfully requested that the references cited on the attached form PTO/SB/08 be considered in the examination of the subject application and that their consideration be made of record.

Applicants respectfully assert that the substantive provisions of 37 CFR §§1.97 and 1.98 are met by the foregoing statement.

Respectfully submitted,

Frank C. Eisenschenk, Ph.D.
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FCE/sl
Attachments: Form PTO/SB/08; copies of references cited therein.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 6

Complete if Known	
Application Number	10/780,948
Filing Date	February 17, 2004
First Named Inventor	Mark D. Erion
Art Unit	1614
Examiner Name	
Attorney Docket Number	MET-016XDT

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. [1]	Document Number Number - Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	U1	US-4,278,791	07-14-1981	Botta et al.	All
	U2	US-5,342,850	08-30-1994	Ohnota et al.	All
	U3	US-6,147,101	11-14-2000	Maeda et al.	All
	U4	US-5,728,704	03-17-1998	Mylari et al.	All
	U5	US-6,054,587	04-25-2000	Reddy et al.	All
	U6	US-6,294,672	09-25-2001	Reddy et al.	All
	U7	US-6,312,662	11-06-2001	Erion et al.	All
	U8	US-			
	U9	US-			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. [1]	Foreign Patent Document Country Code [3] - Number [4] - Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	F1	EP 0354322	06-16-1989	American Cyanamid Company	All	
	F2	WO 99/47549	09-23-1999	Ontogen Corp.	All	
	F3	WO 99/45016	09-10-1999	Metabasis Therapeutics Inc.	All	
	F4	WO 00/27401	05-18-2000	Warner-Lambert Co.	All	
	F5	WO 01/52825	07-26-2001	Novartis AG	All	
	F6	WO 90/08155	07-26-1990	Board of Regents-University of Texas	All	
	F7	WO 90/10636	09-20-1990	Board of Regents-University of Texas	All	

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	R1	AZEN, S.P., *et al.*, "TRIPOD (TRoglitazone In the Prevention of Diabetes): A Randomized, Placebo-Controlled Trial of Troglitazone in Women with Prior Gestational Diabetes Mellitus," *Controlled Clinical Trials*, Vol. 19, Issue 2, Pages 217-231, Elsevier B.V. (April 1998).	
	R2	CHIASSON, J.-L., *et al.*, "Acarbose for the prevention of Type 2 diabetes, hypertension and cardiovascular disease in subjects with impaired glucose tolerance: facts and interpretations concerning the critical analysis of the STOP-NIDDM Trial data," *Diabetologia*, 47: 969-975, Springer-Verlag (2004).	
	R3	DELORME, S., *et al.*, "Acarbose in the prevention of cardiovascular disease in subjects with impaired glucose tolerance and type 2 diabetes mellitus," *Current Opinion in Pharmacology,* 5:184-189, Elsevier (2005).	
	R4	DICKSON, J.K. *et al.*, "Orally Active Squalene Synthase Inhibitors: Bis((acyloxy)alkly) Prodrugs of the α-Phosphonosulfonic Acid Moiety" *J. Med. Chem.* 39: 661-664 American Chemical Society (1996).	
	R5	EGRON, D. *et al.*, "Synthesis and Anti-HIV Activity of Some *S*-Acyl-2-Thioethyl (Sate) Phosphoramidate Derivatives of 3'-Azido-2',3'Dideoxythymidine" *Nucleosides & Nucleotides* 18(4&5): 981-982 Marcel Dekker, Inc. (1999).	
	R6	ERION, M.D. *et al.*, "Computer-Assisted Scanning of Ligand Interactions: Analysis of the Fructose 1,6-Bisphosphatase-AMP Complex Using Free Energy Calculations" *J. Am. Chem. Soc.* 122: 6114-6115 American Chemical Society (2000).	
	R7	ERION, M.D. and REDDY, M.R. "Ligand Interaction Scanning Using Free Energy Calculations" *Free Energy Calculations in Rational Drug Design*, Chapter 11, 225-241 Springer-Verlag (2001).	
	R8	ERION, M.D. *et al.*, "MB06322 (CS-917): A Potent and Selective Inhibitor of Fructose 1,6-Bisphosphatase for Controlling Gluconeogenesis in Type 2 Diabetes" *PNAS* 102(22): 7970-7975 (May 31, 2005).	
	R9	FISHER, J.S. *et al.*, "Glucose transport rate and glycogen synthase activity both limit skeletal muscle glycogen accumulation," *The American Journal of Physiology Endocrinol. Metab.*, Vol. 282, pp. E1214-E1221, American Physiological Society (June 2002).	
	R10	FUJIWARA, T. *et al.*, "Suppression of Hepatic Gluconeogenesis in Long-Term Troglitazone Treated Diabetic KK and C57BL/KsJ-db/db Mice" *Metabolism* 44(4): 486-490 (April 1995).	

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	R11	GIDH-JAIN, M. *et al.*, "The Allosteric Site of Human Liver Fructose-1,6-Bisphosphatase" *Journal of Biological Chemistry*, 269(44): 27732-27738 The American Society for Biochemistry and Molecular Biology, Inc. (1994).	
	R12	HOLMAN, R.R. "Assessing the potential for α-glucosidase inhibitors in prediabetic states," *Diabetes Research and Clinical Practice*, Vol. 40, Supp. 1, Pages S21-S25, Elsevier Ireland Ltd. (July 1998).	
	R13	HULLEY, S. *et al.*, "Randomized Trial of Estrogen Plus Progestin for Secondary Prevention of Coronary Heart Disease in Postmenopausal Women," *J. of Am. Medical Assoc.*, Vol. 280, No. 7, pp. 605-613 (August 19, 1998).	
	R14	INZUCCHI, S.E. *et al.*, "Efficacy and Metabolic Effects of Metformin and Troglitazone in Type II Diabetes Mellitus" *N.E. Journal of Medicine* 338(13): 867-872 Massachusetts Medical Society (March 26, 1998).	
	R15	LINK, J.T. *et al.*, "Pharmacological regulation of hepatic glucose production," *Curr. Opin. Investig. Drugs*, 4(4):421-429 (April 2003).	
	R16	MAGGS, D.G. *et al.*, "Metabolic Effects of Troglitazone Monotherapy in Type 2 Diabetes Mellitus" *Annals of Internal Medicine* 128(3): 176-185 American College of Physicians (February 1, 1998).	
	R17	OKUNO, A. *et al.*, "CS-917, a Fructose 1,6-Bisphosphatase (FBPase) Inhibitor, Suppresses Gluconeogenesis In Vitro and In Vivo by a Different Mechanism than Metformin" poster presented at The American Diabetes Association 66th Scientific Session, Washington, DC (June 2006).	
	R18	PICKAVANCE, L. *et al.*, "The Development of Overt Diabetes in Young Zucker Diabetic Fatty (ZDF) Rats and the Effects of Chronic MCC-555 Treatment" *British Journal of Pharmacology*, 125: 767-770 Stockton Press (1998).	
	R19	POTTER, S.C. *et al.*, "Effect of MB06322, a Potent and Selective Inhibitor of Fructose 1,6-Bisphosphatase, on Gluconeogenesis in the ZDF Rat as Assessed by the Deuterated Water Technique" *DIAEAZ* 52(2): A364, Journal of the American Diabetes Association Abstract No. 1516-P, American Diabetes Association (June 2004).	
	R20	POTTER, S.C. "Evidence Implicating Gluconeogenesis Inhibition as the Mechanism by Which MB06322 Lowers Blood Glucose In Vivo" *DIAEAZ* 52(2): A364, Journal of the American Diabetes Association Abstract No. 1517-P, American Diabetes Association (June 2004).	

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Sheet 4 of 6

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Application Number	10/780,948
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	R21	PRISANT, L.M., "Preventing Type II Diabetes Mellitus," *J. Clin. Pharmacol.,* 44:406-413, American College of Clinical Pharmacology (2004).	
	R22	REDDY, M.R. and ERION, M.D. "Computer Aided Drug Design Strategies Used in the Discovery of Fructose 1,6-Bisphosphatase Inhibitors" *Current Pharmaceutical Design* 11: 283-294 Bentham Science Publishers Ltd. (2005).	
	R23	REDDY, K.R. *et al.*, "Discovery of 2-Aminopyridine Inhibitors of FBPase" abstract for the 230th National American Chemical Society (ACS) Meeting, Washington, DC, Aug./Sept. 2005, ACSMEDI Program and Abstract Book Archives, pp. 197-198, MEDI 323, obtained from http://oasys.acs.org/acs/230nm/medi/staff/separates.cgi 8/8/2005.	
	R24	REDDY, M.R. and ERION, M.D. "Fructose 1,6-Bisphosphatase: Use of Free Energy Calculations in the Design and Optimization of AMP Mimetics" *Free Energy Calculations in Rational Drug Design*, Chapter 14, 285-297 Springer-Verlag (2001).	
	R25	SATHYAPRAKASH, R. *et al.*, "Preventing Diabetes by Treating Aspects of the Metabolic Syndrome," *Current Diabetes Reports*, 2:416-422, Current Science Inc. (2002).	
	R26	SREENAN, S. *et al.*, "Prevention of Hyperglycemia in the Zucker Diabetic Fatty Rat by Treatment with Metformin or Troglitazone" *Am. J. Physiol.* 271 (*Endorcinol. Metab.* 34): E742-E747 American Physiological Society (1996).	
	R27	SRIVASTVA, D.N. and FARQUHAR, D. "Bioreversible Phosphate Protective Groups: Synthesis and Stability of Model Acyloxymethyl Phosphates" *Bioorganic Chemistry* 12: 118-129 Academic Press, Inc. (1984).	
	R28	TORRES, T. *et al.*, "Inhibition of glycogen phosphorylase suppresses basal and glucagon-induced glucose production and increases glucose uptake in the liver of conscious dogs" (Integrated Physiology—Liver 1484-P), *Diabetes*, Vol. 52 i6, p. A343, American Diabetes Association (June 2003).	
	R29	TRISCARI, J. *et al.*, "Multiple Ascending Doses of CS-917, a Novel Fructose 1,6-Bisphosphatase (FBPase) Inhibitor, in Subjects with Type 2 Diabetes Treated for 14 Days" poster presented at The American Diabetes Association 66th Scientific Session, Washington, DC (June 2006).	
	R30	TURNBULL, A. *et al.*, "Pharmacological inhibition of glycogen phosphorylase (GP) lowers plasma glucose in rat models of type 2 diabetes. (Integrated Physiology—Liver 1485-P)," *Diabetes*, Vol. 52 i6, American Diabetes Association (June 2003).	

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	R31	TURNER, R.C. *et al.*, "U.K. Prospective Diabetes Study 16: Overview of 6 Years' Therapy of Type II Diabetes, a Progressive Disease. (U.K. Prospective Diabetes Study Group)" *Diabetes* 44(11): 1249(10) American Diabetes Association (Nov. 1995).	
	R32	VAN POELJE, P.D. *et al.*, "Characterization of the Mechanism of Action and Antidiabetic Activity of MB06322, a Potent and Selective Inhibitor of Fructose 1,6-Bisphosphatase" *DIAEAZ* 52(2): A366, Journal of the American Diabetes Association Abstract No. 1523-P, American Diabetes Association (June 2004).	
	R33	VAN POELJE, P.D. *et al.*, "Comparative Metabolic Effects of a Novel Fructose 1,6-Bisphosphatase Inhibitor and Metformin in the Female ZDF Rat", Abstracts of the 41st Annual Meeting of The European Association for the Study of Diabetes, Athens, Greece *Diabetologia* 48(1): A278 Abstract No. 765 Springer-Verlag (August 2005).	
	R34	VAN POELJE, P.D. *et al.*, "Inhibition of Fructose 1,6-Bisphosphatase Reduces Excessive Endogenous Glucose Production and Attenuates Hyperglycemia in Zucker Diabetic Fatty Rats" *Diabetes* 55: 1747-1754, American Diabetes Association (June 2006).	
	R35	VAN POELJE, P.D. *et al.*, "MB06322 (CS-917) Lowers Blood Glucose in Rodents by Inhibiting Both Hepatic and Renal Gluconeogenesis" *DIAEAZ* 55(1): A137, Journal of the American Diabetes Association Abstract No. 575-P, American Diabetes Association (June 2006).	
	R36	VAN POELJE, P.D. *et al.*, "Fructose 1,6-Bisphosphatase Inhibition Enhances the Antidiabetic Activity of Insulin Sensitizers in the ZDF Rat" *DIAEAZ* 52(2): A366, Journal of the American Diabetes Association Abstract No. 1524-P, American Diabetes Association (June 2004).	
	R37	VAN POELJE, P.D. "MB06322, a Potent Inhibitor of Gluconeogenesis, Attenuates Hyperglycemia without Causing Weight Gain or Hypoglycemia in Female Zucker Diabetic Fatty Rats" *DIAEAZ* 54(1): A124, Journal of the American Diabetes Association Abstract No. 503-P, American Diabetes Association (June 2005).	
	R38	WALKER, J. *et al.*, "Safety and Tolerability of Single Doses of CS-917, a Novel Gluconeogenesis Inhibitor, in Normal Male Volunteers" *DIAEAZ* 55(1): A463, Journal of the American Diabetes Association Abstract No. 2002-PO, American Diabetes Association (June 2006).	
	R39	WALKER, J. *et al.*, "Safety, Tolerability and Pharmacodynamics of Multiple Doses of CS-917 in Normal Volunteers" *DIAEAZ* 55(1): A464, Journal of the American Diabetes Association Abstract No. 2003-PO, American Diabetes Association (June 2006).	

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	R40	YOSHIDA, T. *et al.*, "Comparison of Acute and Chronic Glucose-Lowering Effect of CS-917, a Fructose 1,6-Bisphosphatase (FBPase) Inhibitor, and Metformin in Rat Models of Type 2 Diabetes" poster presented at The American Diabetes Association 66th Scientific Session, Washington, DC (June 2006).	
	R41	YOSHIDA, T. *et al.*, "CS-917, a Fructose 1,6-Bisphosphatase Inhibitor, Has Glucose-Lowering Effects in Cynomolgus Monkeys and Improves Postprandial Hyperglycemia in Goto-Kakizaki (GK) Rats" *DIAEAZ* 54(1): A116, Journal of the American Diabetes Association Abstract No. 472-P, American Diabetes Association (June 2005).	
	R42		
	R43		
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	R46		
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